REMARKS

Favorable reconsideration of this application as presently amended is respectfully requested. Claims 1- 12, 14-16 and 18 - 22 are pending. In this Amendment, claims 14 – 16 are canceled and claims 1-3 and 18 are amended. No new matter is added.

Support for the addition of "coating said gastric material with said first composition, moisture in said gastric material causing said first composition to stick to said gastric material;" in claim 1 is found at Page 7, lines 14 – 16 and page 13, lines 22 – 23 and elsewhere within the specification.

Support for the addition of "to increase efficiency" in claims 2, 19 and 20 is found at Page 8, lines 10 – 12 and elsewhere within the specification.

Support for the addition of "mixing said gastric material with said dry, finely powered urea and said dry finely powered indicator, moisture in said gastric material causing said dry, finely powered urea and said dry finely powered indicator to stick to said sample and activate said indicator," is found at Page 13, lines 21 – 23 and elsewhere within the specification.

Support for the amendments to Claims 3 and 21 is found at page 9, lines 5 – 11 and elsewhere within the specification.

The Examiner has stated that the claims submitted in the amendment are inconsistent with the claims previously submitted, citing Claim 14. Claims 14 – 16 have been cancelled and are no longer pending in the application. A copy of the compliant amendment filed in response to the Notice of Non-Compliant Amendment dated September 22, 2004 is appended hereto for the Examiner's reference.

35 U.S.C. 102 Rejection

Claims 1, 3, 6, 8, 9, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothgang.

As stated in the prior Amendment, Rothgang does teach the use of a dry urea, preferably in a compressed product although the powdered form can be placed in capsules, blister packs, etc. In each of the embodiments, as taught by Rothgang, water is added to the urea to initiate the reaction process. (Page 5, lines 17 – 18; lines 24 – 25 – page 6, lines 1 – 7).

Currently pending independent Claim 1 has been amended to clearly state that the gastric material is contacted directly with the dry, finely powered urea and that the urea sticks due to moisture inherent in the sample. As Rothgang does not teach the use of a dry, finely powered urea or the absence of water, it is respectfully submitted that the rejection of Claim 1 based on Rothgang is overcome.

The Examiner states that on Page 7, line 1 of the Rothgang patent, phenol red is taught as an indicator. It is submitted that applicant is not claiming the invention of phenol red as an indicator, but rather is claiming phenol red in combination with the novel method of claim 1. Claim 10 depends directly from claim 1, and, accordingly, includes all of the patentable features of claim 1. Therefore, claim 10 is patentable over Rothgang for the reasons discussed above with respect to claim 1.

Rothgang on page 7, first paragraph states that the indicator may be separate from other components and on page 9 – 10, that the pH indicator can be located apart from the other components. The separation of components is not novel, especially in the research area and applicant is not claiming the act of separating components. Applicant is rather, claiming the separation of the indicator from the dry, finely powdered urea as claimed in claim 1. Claim 8 depends directly from claim 1, and, accordingly, includes all of the patentable features of claim 1. Therefore, claim 8 is patentable over Rothgang for the reasons discussed above with respect to claim 1.

Claims 2, 4, 5, 7, 12, 14-16, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rothgang in view of King.

Claims 14-16 have been cancelled.

The Examiner states that the King patent teaches the user of an indicator in a gel form and that, when combined with the Rothgang, would produce the urea composition and gel indicator composition of the instant invention. As stated heretofore, and clearly set forth in the pending claims, the Rothgang patent does not directly contact the specimen with a dry, finely powered urea composition, creating a fundamental difference between the Rothgang patent and the pending application. It is respectfully submitted that the use of a gel indicator would not overcome the basic differences between the Rothgang patent and the pending application.

The use of a gel indicator is disclosed in dependent claim 4. Claim 4 depends directly from claim 1, and, accordingly, includes all of the patentable features of claim 1. Therefore, claim 4 is patentable over Rothgang for the reasons discussed above with respect to claim 1.

With respect to the use of agar to form gelatinous materials, this is well known in the medical arts and, in of itself, is not patentable. The use of agar in a unique combination, however, is patentable when used as a limitation for a patentable method. The use of agar is disclosed in dependent claim 5. Claim 5 depends directly from claim 1, and, accordingly, includes all of the patentable features of claim 1. Therefore, claim 5 is patentable over King for the reasons discussed above with respect to claim 1.

The Examiner has stated that regarding the particle sizes of urea, no function is attributed to the particle size.

In the instant invention fine particle size is advantageous. As stated on page 8, lines 8 – 11, the sample is contacted with the urea composition, causing the urea to stick to the sample. As stated in the specification at page 7, lines 13-17, as the moisture inherent in the sample causes the powdered urea to adhere, the sample is able to be coated, or floured, with the urea composition thereby covering the sample with urea. The specification specifically teaches at page 8, lines 17 – 19, that the smaller the particle size, the more particles adhere to the sample and the more efficient the test.

The reaction starts because the urea is destroyed by any bacteria in the sample. The sample is then placed into the indicator composition where any urease reacts with the urea to change the pH and turn the coated sample the appropriate indicator color.

Under Rothgang's teachings the urea would not be in a form that could coat a sample and therefore Rothgang would not be concerned about particle size. Nor would Rothgang have the quantity of concentrated urea around the sample to react with the urease, providing a less visible reaction. Additionally, the water added to the urea further dilutes the intensity of the reagent reaction.

Dependent claims 2, 19 and 20 have been amended to clearly state that the smaller particle size increases efficiency.

CONCLUSION

If the Examiner has any questions or concerns regarding the present response, the Examiner is invited to contact Sheldon Parker at 703-563-2041, Ext. 2041.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited.

Respectfully submitted,

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January 13, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/977,555
Applicant	:	BARRY J. MARSHALL *ET AL*
Filed	:	OCTOBER 15, 2001
Title	:	METHOD FOR DETECTION OF UREASE AND METHOD FOR USING SAME
Art Unit	:	1651
Examiner	:	GITOMER, RALPH
Atty Docket No.	:	VAL-99A (16843)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Notice of Non-Compliant Amendment of September 22, 2004, the period of response to which is set to expire on October 22, 2004, please amend the above-captioned application, without prejudice or disclaimer, as follows:

Amendments to the Claims begin on page 2 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for detecting the presence of urease in a gastrointestinal system comprising:

providing a sample of gastric material from a patient;

contacting said gastric material with a first powdered composition located in a first area, said first powdered composition being ~~comprising~~ urea, said urea ~~being capable of being converted into~~ converting to ammonia when contacted with urease; ~~and~~

removing at least a portion of said gastric material from said first area; and

~~thereafter~~ contacting said gastric material with a second composition located in a second area, said second composition comprising ~~an~~ at least one indicator, said indicator being configured to indicate the presence of ammonia thereby indicating the presence of urease in said gastric material.

2. (Original) A method as defined in claim 1, wherein said urea has a mean particle size of less than 0.1 mm.

3. (Currently Amended) A method as defined in claim 1, wherein said first composition further comprises ~~an~~ a powdered anti-caking agent.

4. (Original) A method as defined in claim 1, wherein said second composition comprises a gel.

5. (Currently Amended) A method as defined in claim 1, wherein said second composition further comprises agar ~~in addition to said indicator~~.

6. (Currently Amended) A method as defined in claim 1, wherein said indicator ~~comprises~~ is a pH indicator that changes color when the pH is increased.

7. (Original) A method as defined in claim 1, wherein said urea has a mean particle size of less than about 0.05 mm.

8. (Original) A method as defined in claim 1, wherein said first composition and said second composition are positioned in the same container in a spaced apart relationship.

9. (Original) A method as defined in claim 1, wherein said second composition further comprises a bactericide or a bacteristat.

10. (Currently Amended) A method as defined in claim 1, wherein said indicator ~~comprising~~ is phenol red.

11. (Original) A method as defined in claim 1, wherein said second composition further comprises a pH adjuster.

12. (Original) A method as defined in claim 2, wherein said second composition further comprises agar and a pH adjuster.

13. (Cancelled) ~~A method as defined in claim 1, wherein said gastric material is contacted with said first composition such that at least a portion of the urea is combined with the gastric material prior to being removed from said first composition and contacted with said second composition.~~

14. (Currently Amended) A method for detecting the presence of urease in a gastrointestinal system comprising the steps of:

providing a sample of a gastric biopsy material from a patient;

contacting said gastric material with a first composition ~~comprising~~ of urea located in a first area, said urea being capable of being converted into ammonia when contacted with urease;

removing at least a portion of said gastric material from said first area; and

~~thereafter~~ contacting said gastric biopsy material with a second composition, located in a second area, comprising an indicator contained in a gel, said indicator being configured to change color for indicating the presence of urease in said gastric material.

15. (Currently Amended) A method as defined in claim 14, wherein said urea is ~~present as~~ a powder ~~in said first composition~~.

16. (Currently Amended) A method as defined in claim 15, wherein said second composition further comprises agar and a pH adjuster, and wherein said indicator ~~comprises~~ is phenol red.

~~17. (Cancelled) A method as defined in claim 14, wherein said gastric material is contacted with said first composition such that at least a portion of the urea is combined with the gastric material prior to being contacted with said second composition.~~

18. (Currently Amended) A method for detecting the presence of urease in a gastrointestinal system comprising the steps of:

providing a sample of gastric material from a patient;

contacting said gastric material with a composition comprising a powdered urea and a dry, powdered, indicator, said urea being capable of being converted into ammonia when contacted with urease and said indicator being configured to indicate the presence of ammonia thereby indicating the presence of urease in said gastric material.

19. (Original) A method as defined in claim 18, wherein said urea present within said composition has a mean particle size of less than about 0.1 mm.

20. (Original) A method as defined in claim 18, wherein said urea present within said composition has a mean particle size of less than about 0.05 mm.

21. (Original) A method as defined in claim 18, wherein said composition further

comprises an anti-caking agent.

22. (Original) A method as defined in claim 18, wherein said indicator comprises a pH indicator that changes color when the pH is increased.

If the Examiner has any questions or concerns regarding the present response, the Examiner is invited to contact Sheldon H. Parker, 434-817-6606.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited.

Respectfully submitted,

_____

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January 13, 2005